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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,377	06/09/2000	ZHONGYI LI	054270/0126	7408

22428 7590 07/02/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,377

Applicant(s)

LI ET AL.

Examiner

Stuart F. Baum

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48 to 68 is/are pending in the application.
- 4a) Of the above claim(s) 55,57,58,63-65,67 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-54,56,59-62 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The amendment filed 4/24/2003 has been entered.

Claims 48 to 68 are pending.

Claims 23-47 have been canceled.

Claims 48 to 68 have been newly added.

2. Newly submitted claims 55, 57-58, 63-65, and 67-68 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 55, 57-58, and 64-65 are drawn to nucleic acid sequences in antisense orientation and methods of decreasing expression of starch branching enzyme II, claim 63 is drawn to a chimeric protein, claim 67 is drawn to a product and claim 68 is drawn to a method of modulating the time of expression of a starch branching enzyme II. All of the before mentioned claims are drawn to an invention not elected in the response to the restriction requirement filed 7/22/2002.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55, 57-58, 63-65, and 67-68 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 48-54, 56, 59-62, and 66 are examined in the present office action.

Art Unit: 1638

4. This application contains claims 55, 57-58, 63-65, and 67-68 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancelation of nonelected claims (37 CFR 1.144) See MPEP § 821.01.
5. Rejections and objections not set forth below are withdrawn.
6. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Information Disclosure Statement

7. Applicant states in the response that Australian Patent No. 48747/97 (5/14/1998) has been submitted for consideration. The only two submitted documents are WO 97/20040 and Australian Patent No. 730900. The WO 97/20040 has been included on the IDS form 1449 along with the Morrell et al reference. A copy of the IDS form 1449 is included with the present office action.

Indefiniteness

8. Claims 56, 60-61, and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 56, the term "altering" is unclear. Applicant needs to explicitly state how the expression of starch branching enzyme II has been changed.

In claim 56, 2nd line, insert the word --to-- before the word "claim".

Art Unit: 1638

In claim 60, the metes and bounds of "propagating material" have not been defined. All subsequent recitations of "propagating material" are also rejected.

In claim 66, the term "altered" is unclear. Applicant needs to explicitly state how the starch has been changed.

Utility

9. Claims 48-54, 56, 59-62, and 66 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/24/2002. Applicant's arguments filed 4/24/2003 have been fully considered but they are not persuasive.

Applicants contend that SEQ ID NO:10 which encodes a starch branching enzyme II (SBE II) shares homology to other SBE II sequences and encodes a translation product with characterized SBE II activity. Applicants reiterate data from the specification which states that the SBE II-D1 clone from wheat exhibited sequence identity to the N-terminal region of a SBE as disclosed by Morrell et al (1997). Applicants conclude that the knowledgeable reader of the present specification would therefore interpret SEQ ID NO:10 to have defined SBE II activity.

As evidence that Applicant's disclosed SEQ ID NO:12 is a SBE II polypeptide, Applicants contend that their SEQ ID NO:12 exhibits sequence identity to other starch branching enzymes. Given that a closer look at the presented data only indicates that 13 of the 768 amino acids of SEQ ID NO:12 share identity with the N-terminal region of other starch branching enzymes, and given that it has not been disclosed if the catalytic site for the starch branching

Art Unit: 1638

enzyme is contained in the N-terminal region of the polypeptide, and given that Applicants isolated their invention by a weak sequence hybridization to a maize starch branching enzyme II and given that Applicants have not verified the starch branching enzyme activity of their polypeptide, Applicant's invention is not supported by either a credible asserted utility or well established utility.

10. Claim 61 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 61 is drawn to a seed of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only two thirds of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny (seeds), it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy, Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the seeds comprise the construct that was introduced into the parent seed would overcome the rejection.

Written Description

11. Claims 48-50, 52-54, 56, 59-62, and 66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

Art Unit: 1638

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/24/2002. Applicant's arguments filed 4/24/2003 have been fully considered but they are not persuasive.

Applicants contend that the specification clearly identifies structural and functional domains that are unique to the SBE II protein encoded by SEQ ID NO:10, and they reference Table 2, page 38 of the specification (page 5, 3rd paragraph of Applicants response). Applicants further contend that the specification discloses the "overall function" of SBE II, which is involved in the production of glucose alpha-1,6 branches characteristic of amylopectin.

The Office contends that Applicant's claims are drawn to a genus encompassing SBE II but Applicant has only disclosed a few basic structural features of the wheat endosperm SBE II gene, including the promoter. Applicant has not fully described the genus which would include for example, those amino acids involved in the catalytic domain(s) of the enzyme. In addition, Applicants disclose that the SBE II gene comprises 22 exons which are encoded by a genomic sequence spanning base numbers 1058 to 11475, but Applicants only disclose 11463 bases in SEQ ID NO:10. Given the lack of the full genomic sequence, Applicants are not in possession of the claimed invention.

Enablement

12. Claims 48-54, 56, 59-62, and 66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

Art Unit: 1638

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments are duplicative of those previously stated above. Therefore this rejection is maintained for the reasons of record set forth in the Official action mailed 10/24/2002. Applicant's arguments filed 4/24/2003 have been fully considered but they are not persuasive.

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1638

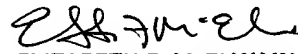
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

June 24, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600